

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UMB BANK, N.A., solely in its capacity :
as Trustee under the Contingent Value :
Rights Agreement by and between :
Bristol-Myers Squibb Company and : ORAL ARGUMENT REQUESTED
Equiniti Trust Company, dated as of :
November 20, 2019, :
Plaintiff, :
v. : Case No. 1:21-cv-04897 (JMF)
BRISTOL-MYERS SQUIBB COMPANY, :
Defendant. :
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**MEMORANDUM OF LAW IN SUPPORT OF THE MOTION OF DEFENDANT
BRISTOL-MYERS SQUIBB COMPANY TO DISMISS THE COMPLAINT**

John J. Clarke, Jr.
Jessica A. Masella
Jessica Park Wright
DLA PIPER LLP (US)
1251 Avenue of the Americas
New York, New York 10020
(212) 335-4500

Attorneys for Defendant
Bristol-Myers Squibb Company

Dated: July 23, 2021

Table of Contents

	<u>Page</u>
INTRODUCTION	1
BACKGROUND	4
A. The Parties	4
B. The CVR Agreement	4
C. The Liso-cel Application	6
D. The Trustee's Request to Examine Records	9
E. The Claims Asserted and the Trustee's Untimely Notice.....	10
MOTION TO DISMISS STANDARD.....	10
ARGUMENT	11
I. THE ADMITTED FAILURE TO PROVIDE TIMELY PRE-SUIT NOTICE REQUIRES DISMISSAL OF THE TRUSTEE'S "DILIGENT EFFORTS" CLAIM.....	11
A. New York Law on Motions to Dismiss Breach of Contract Claims.....	11
B. The Trustee's Failure to Plead an Event of Default for Alleged Breach of the Diligent Efforts Provision Requires Dismissal.....	12
II. THE CLAIM FOR ALLEGED REFUSAL TO PERMIT EXAMINATION OF THE COMPANY'S BOOKS AND RECORDS ALSO SHOULD BE DISMISSED.....	18
CONCLUSION.....	21

Table of Authorities

	<u>Page(s)</u>
<u>Cases</u>	
<i>100 Orchard St., LLC v. Travelers Indem. Ins. Co. of Am.,</i> No. 20 Civ. 8452 (JMF), 2021 WL 2333244 (S.D.N.Y. June 8, 2021)	8
<i>Accent Delight Int'l Ltd. v. Sotheby's,</i> 394 F. Supp. 3d 399 (S.D.N.Y. 2019).....	4
<i>Ashcroft v. Iqbal,</i> 556 U.S. 662 (2009).....	10
<i>Bausch & Lomb Inc. v. Bressler,</i> 977 F.2d 720 (2d Cir. 1992).....	17
<i>Bell Atl. Corp. v. Twombly,</i> 550 U.S. 544 (2007).....	10, 11
<i>BNP Paribas Mortg. Corp. v. Bank of Am., N.A.,</i> 866 F. Supp. 2d 257 (S.D.N.Y. 2012).....	12
<i>Cont'l Ins. Co. v. Atl. Cas. Ins. Co.,</i> 603 F.3d 169 (2d Cir. 2010).....	12
<i>Diesel Props. S.r.l. v. Greystone Bus. Cred. II LLC,</i> 631 F. 3d 42 (2d Cir. 2011).....	11
<i>DiFolco v. MSNBC Cable L.L.C.,</i> 622 F.3d 104 (2d Cir. 2010).....	4
<i>E. 18th Mgmt. Corp. v. CSC ServiceWorks, Inc.,</i> No. 18 Civ. 4068 (NGG), 2019 WL 2994447 (E.D.N.Y. July 9, 2019)	13, 17, 18
<i>I.J. Litwak & Co. v. Gen. Signal Corp.,</i> 741 N.Y.S.2d 426 (2d Dep't 2002).....	13, 17
<i>Int'l Techs. Mktg., Inc. v. Verint Sys. Ltd.,</i> 157 F. Supp. 3d 352 (S.D.N.Y. 2016), <i>aff'd</i> , 850 F. App'x 38 (2d Cir. 2021).....	15
<i>Kass v. Kass,</i> 91 N.Y.2d 554, 673 N.Y.S.2d 350 (1998)	16
<i>K. Bell & Assocs. v. Lloyd's Underwriters,</i> 97 F.3d 632 (2d Cir. 1996).....	11

	<u>Page(s)</u>
<i>Kenford Co. v. Co. of Erie</i> , 67 N.Y.2d 257, 502 N.Y.S.2d 131 (1986).....	20-21
<i>Lockheed Martin Corp. v. Retail Holdings NV</i> , 639 F.3d 63 (2d Cir. 2011).....	16
<i>Nat'l Mkt. Share Inc. v. Sterling Nat'l Bank</i> , 392 F. 3d 520 (2d Cir. 2004).....	11, 20
<i>N.Y. Wheel Owner LLC v. Mammoet Hldg. B.V.</i> , 481 F. Supp. 3d 216 (S.D.N.Y. 2020).....	12, 13
<i>Olin Corp. v. Am. Home Assur. Co.</i> , 704 F.3d 89 (2d Cir. 2012).....	12
<i>OneWest Bank, N.A. v. Lehman Bros. Holding Inc.</i> , No. 14 Civ. 8916 (JMF), 2015 WL 1808947 (S.D.N.Y. Apr. 20, 2015).....	10
<i>Oppenheimer & Co. v. Trans Energy, Inc.</i> , 946 F. Supp. 2d 343 (S.D.N.Y. 2013).....	10-11
<i>Point Prods. A.G. v. Sony Music Ent. Inc.</i> , No. 93 Civ. 4001 (NRB), 2000 WL 1006236 (S.D.N.Y. July 20, 2000).....	18
<i>Prudential Ins. Co. of Am. v. Hilton Hotel Corp.</i> , No. 95 Civ. 5575 (KMW), 1996 WL 34002 (S.D.N.Y. June 19, 1996).....	13
<i>Rojas v. Don King Prods., Inc.</i> , No. 11 Civ. 8468 (KBF), 2012 WL 760336 (S.D.N.Y. Mar. 6, 2012)	<i>passim</i>
<i>Svensson v. Securian Life Ins. Co.</i> , 706 F. Supp. 2d 521 (S.D.N.Y. 2010).....	11
<i>Tellabs, Inc. v. Makor Issues & Rights, Ltd.</i> , 551 U.S. 308 (2007).....	4
<i>Twitchell v. Town of Pittsford</i> , 483 N.Y.S.2d 524, 525 (4th Dep't 1984), <i>aff'd mem.</i> 66 N.Y.2d 824 (1985)	15
<i>UMB Bank, N.A. v. Neiman Marcus Grp., Inc.</i> , 128 N.Y.S.3d 823 (N.Y. Sup. Ct. 2020).....	14
<i>U.S. Bank Nat'l Ass'n v. U.S. Timberlands Klamath Falls L.L.C.</i> , C.A. No. 112-N, 2004 WL 1699057 (Del. Ch. July 29, 2004)	<i>passim</i>
<i>USI Ins. Servs. LLC v. Miner</i> , 801 F.Supp.2d 175 (S.D.N.Y. 2011).....	17

	<u>Page(s)</u>
<i>Vision Entm't Worldwide, LLC v. Mary Jane Prods., Inc.,</i> No. 13 Civ. 4215 (AT), 2014 WL 5369776 (S.D.N.Y. Oct. 17, 2014)	17-18
<i>Wakeman v. Wheeler & Wilson Mfg. Co.,</i> 101 N.Y. 205 (1886)	20
<i>Wallace v. 600 Partners Co.,</i> 86 N.Y.2d 543, 634 N.Y.S.2d 669 (1995)	12
<i>Wolff & Munier, Inc. v. Whiting-Turner Contracting Co.,</i> 946 F.2d 1003 (2d Cir.1991).....	18
<u>Statutes and Rules</u>	
28 U.S.C. § 1332(a)(1).....	4
Fed. R. Civ. P. 12(b)(6).....	4, 10
Fed. R. Evid. 201	8
<u>Other Authorities</u>	
Igor Kirman and Victor Goldfeld, <i>Contingent Value Rights</i> , Practical Law (2020)	4
Executive Office of the President, Proclamation 9994, 85 Fed. Reg. 15337 (Mar. 13, 2020)	8

Bristol-Myers Squibb Company (“BMS” or the “Company”) respectfully submits this memorandum of law in support of its motion to dismiss the complaint for failure to state a claim.

INTRODUCTION

When a contract requires the provision of notice and an opportunity to cure alleged breaches of that contract as a condition precedent to bringing or maintaining a claim, “courts will enforce that agreement.” *Rojas v. Don King Prods., Inc.*, 2012 WL 760336, at *2 (S.D.N.Y. Mar. 6, 2012). This rule is applied even more strictly when, as here, the plaintiff is a trustee whose authority to sue is circumscribed by the terms of the agreement. These established principles of New York law require dismissal of the breach of contract claims in this case.

The contract is the Contingent Value Rights Agreement dated as of November 20, 2019 (the “CVR Agreement”), which BMS entered into in connection with its merger with Celgene Corporation. The CVR Agreement governed a series of contingent value rights (“CVRs”) that would pay holders \$9 per CVR if – but only if – the U.S. Food and Drug Administration (“FDA”) approved applications for three different product candidates by their contractual “milestone” dates.

The FDA approved all three applications largely within the time-frames contemplated in the CVR Agreement. *See* Compl. ¶¶ 17, 19, 51, 80; *id.* ¶¶ 29-32. But the FDA’s approval of the Company’s application for liso-cel (Breyanzi[®]), a treatment for non-Hodgkins lymphoma, came 36 days too late for CVR holders to receive payment. When the liso-cel milestone date passed on December 31, 2020 without an FDA decision on that application, the CVR Agreement automatically terminated without “further action of any [p]arty” and the CVRs were delisted. CVR Agreement, § 1.16; *see* Compl. ¶ 79.

At the behest of opportunistic investors seeking to convert their investment loss into a litigation recovery, the plaintiff UMB Bank, N.A. (the “Trustee”) was appointed as the successor to the original trustee. Compl. ¶ 22. The Trustee’s complaint asserts that the Company engaged

in “blatant misconduct” amounting to a breach of the CVR Agreement because – even though all three applications were approved by the FDA – liso-cel was approved five weeks too late for CVR holders to be paid. *Id.* ¶ 1. The Trustee asserts that BMS breached the CVR Agreement by allegedly failing to use “Diligent Efforts” to obtain FDA approval of liso-cel by the milestone date and allegedly refusing to respond to the Trustee’s last-minute request to examine books and records. *Id.* ¶¶ 87-105.

Although not one of the grounds for dismissal raised on this motion, the complaint provides a false narrative that ignores the Company’s substantial work to bring groundbreaking treatments to patients who need them in the midst of the worst pandemic in a century. The timing of the FDA’s approval of liso-cel was not the result of any failure of “efforts” by BMS or its dedicated employees and contractors. The FDA was not bound by the contractual milestone dates, and the risk that there would be no payment for CVR holders was inherent in the CVR Agreement. *See id.* ¶ 3 (no CVR payment if any of three milestone dates were missed “even by a day”). Moreover, the milestone dates were agreed to long before the COVID-19 pandemic. Tellingly, and illustrating the pandemic’s impact, the FDA has approved *only two* new biologics applications during its current fiscal year – liso-cel and ide-cel – which are the same two applications the Trustee accuses BMS of delaying through “blatant misconduct.” However, factual disputes such as these need not be addressed to dismiss the complaint in its entirety – and to avoid any doubt, BMS is not raising them now.

Instead, the Trustee’s breach of contract claims should be dismissed because it did not provide BMS timely notice of the purported breaches of the CVR Agreement and the opportunity to cure them before litigation was filed, as the contract unambiguously requires. *See*

CVR Agreement, §§ 8.1(b).¹ As a result, the alleged breaches never became an “Event of Default,” *id.*, and the Trustee never obtained the contractual authority to sue, *id.* § 8.4; *see U.S. Bank Nat'l Ass'n v. U.S. Timberlands Klamath Falls L.L.C.*, 2004 WL 1699057, at *3 (Del. Ch. July 29, 2004) (applying New York law) (“without an Event of Default, the Trustee has no power to bring any claim.”). The complaint tacitly acknowledges these requirements. *See* Compl. ¶¶ 92-94, 101-03.

The complaint alleges that the Trustee did not send the required written notice of default to BMS until March 4, 2021, *id.* ¶ 86, *two months after* the CVR Agreement automatically terminated, *see* CVR Agreement, § 1.16. That untimely notice was not, and could not be, effective. After termination, the Company’s alleged breaches could not “continu[e] . . . for a period of ninety (90) days” following the notice, CVR Agreement, § 8.1(b), because the Company had no surviving “obligations” to use Diligent Efforts or to permit the Trustee to examine books and records, CVR Agreement, § 1.16; *see id.* §§ 4.2(f), 7.8. The putative breaches therefore could not “ripen[]” into an Event of Default, as the complaint erroneously asserts. *See* Compl. ¶¶ 93-94, 102-03. Further, by the time of the Trustee’s notice not only had the milestone date passed but also the FDA already had approved liso-cel. No amount of “efforts” could have altered those existing facts.

The Trustee’s failure to comply with the requirements of the CVR Agreement before filing suit requires dismissal of the complaint in its entirety. Its claim for alleged breach of its right to examine “pertinent books and records” also should be dismissed for additional reasons that are discussed below.

¹ A copy of the CVR Agreement is attached as Exhibit A to the complaint. [ECF No. 1-1]

BACKGROUND²

A. The Parties

This is a diversity action. Compl. ¶ 24; *see* 28 U.S.C. § 1332(a)(1). BMS is a global biopharmaceutical company whose mission is to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases. It is incorporated in Delaware with its principal place of business in New York. Compl. ¶ 23. The Trustee is a national bank based in Kansas City, Missouri that in December 2020 was appointed by CVR holders as the successor trustee under the CVR Agreement. *Id.* ¶ 22; *see* CVR Agreement, § 4.10(e). The Trustee asserts claims against BMS for alleged breaches of the CVR Agreement, purportedly “for the benefit of the holders of CVRs.” *See* Compl. ¶ 22.

B. The CVR Agreement

Contingent value rights are complex securities sometimes used in public mergers “to bridge valuation gaps relating to uncertain future events.” Igor Kirman and Victor Goldfeld, *Contingent Value Rights*, Practical Law (2020). In this instance, the “uncertain future events” were approvals by the FDA of several product candidates that still were in development by Celgene in late December 2018 when BMS and Celgene were negotiating the terms of a potential merger. Compl. ¶¶ 29-32.

² Well-pleaded factual allegations of the complaint are assumed to be true solely for purposes of this motion to dismiss. “In considering a motion to dismiss for failure to state a claim pursuant to [Federal] Rule [of Civil Procedure] 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint.” *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010); *see also Accent Delight Int'l Ltd. v. Sotheby's*, 394 F. Supp. 3d 399, 408 (S.D.N.Y. 2019) (Furman, J.) (considering tolling agreement on motion to dismiss because it was “integral” to the complaint). The district court also may consider “matters of which a court may take judicial notice.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

On January 3, 2019, BMS and Celgene agreed to a merger transaction under which BMS would acquire Celgene for consideration consisting of \$50 in cash, one share of BMS common stock, and one CVR for each share of Celgene common stock. *Id.* ¶ 36. Each CVR would provide holders a contingent right to receive \$9 in cash, *but only if* the FDA approved three applications on or before the milestone dates agreed to in the CVR Agreement, specifically: (i) the biologics license application (“BLA”) for liso-cel (referred to as JCAR017) by December 31, 2020; (ii) the new drug application for ozanimod, a treatment for relapsing multiple sclerosis, by December 31, 2020; and (iii) the BLA for ide-cel (referred to as BB2121) by March 31, 2021. *Id.* ¶ 31; *see* CVR Agreement, § 3.1(c). The FDA was not a party to the CVR Agreement and was not bound by these contractual deadlines.

As the complaint explains, if any one of the three FDA approval milestone dates was missed, “*even by a day*,” holders of the CVRs would receive no payment. *Id.* ¶ 3 (emphasis added). In those circumstances, the CVR Agreement would terminate “automatically and without any further action of any [p]arty,” the agreement would “be of no force or effect[,] and the [p]arties” would “have no liability or obligations [t]hereunder[.]” CVR Agreement, § 1.16.

The Company did not enter into the CVR Agreement until November 20, 2019, ten months after the merger agreement, when the Celgene merger became effective. *Id.* ¶¶ 36, 38. The CVRs then were listed and began to trade on the NYSE. *See id.* ¶ 79. Because of their “binary structure,” *id.* ¶ 33, the CVRs traded at a substantial discount to their notional payment amount, *see id.* ¶ 56, reflecting the market’s understanding of the substantial risk that the FDA might not approve one or more of the applications by the applicable deadline in the CVR Agreement.³

³ Similarly, the merger proxy statement issued in late February 2019 recognized the substantial risk that the deadlines might not be met. It included a preliminary fair value of \$3.75 per CVR based on the merger parties’ estimate of the CVRs’ present value after taking into

The FDA approved the new drug application for ozanimod (Zeposia[®]) on March 26, 2020 – four months after the Celgene merger closed and long before its milestone date. *Id.* ¶ 51. The FDA approved the BLA for ide-cel (Abecma[®]), a treatment for multiple myeloma, on March 26, 2021, five days before its milestone date. *Id.* ¶ 19. The FDA also approved the application for liso-cel, on February 5, 2021, but that approval came five weeks after the applicable milestone date. *Id.* ¶¶ 17, 80.

Because the FDA did not approve liso-cel by December 31, 2020, the conditions to payment on the CVRs were not met. By its terms, the CVR Agreement terminated at 12:01 a.m. on January 1, 2021 without further action of any party. *See* CVR Agreement, § 1.16. As a result, the agreement was of no further “force or effect” and the parties to the agreement had “no liability or obligations” thereunder.⁴ *Id.* The CVRs were delisted thereafter. Compl. ¶ 79.

C. The Liso-cel Application

In the CVR Agreement, BMS agreed to “use Diligent Efforts to achieve the Milestone[s].” *Id.* ¶ 5; CVR Agreement, § 7.8. The complaint asserts that if the Company had used Diligent Efforts, “it would have avoided the thirty-six day delay” in obtaining FDA approval for liso-cel and holders of the CVRs would have received \$9 per CVR. Compl. ¶¶ 18, 80-81.

Both liso-cel and ide-cel are types of cell therapy, which is an emerging and complex biotechnology. The FDA has approved only five cell therapy applications, including the

account “the probability of achieving all three necessary approvals[.]” bit.ly/3zjG3t2 (joint proxy statement dated Feb. 22, 2019, as filed on sec.gov) at 68.

⁴ As discussed further below, certain enumerated provisions “survive termination” of the CVR Agreement, but neither the covenant to use Diligent Efforts in section 7.8 nor the obligation to permit the Trustee to examine books and records in section 4.2(f) is included in that carve-out. *See* CVR Agreement, § 1.16.

applications for liso-cel and ide-cel.⁵ *See id.* ¶¶ 18, 82. Liso-cel is used for treatment of patients with large B-cell non-Hodgkin's lymphoma for whom prior treatments have not been successful. *Id.* ¶¶ 1, 39. It is “a chimeric antigen receptor T-cell therapy (‘CAR-T Therapy’)” that is produced “by extracting a cancer patient’s T-cells, . . . genetically modifying them to target and kill B-cells that have become malignant, and then injecting the genetically modified T-cells into the patient” with a lentiviral vector. *Id.* ¶ 39.

The Trustee alleges that BMS made “highly atypical” decisions about the supporting data included in the final module of the liso-cel application, addressing Chemistry, Manufacturing and Controls (“CMC”), and therefore failed to use “Diligent Efforts.” *Id.* ¶¶ 7, 52. The complaint does not allege that the alleged omissions caused the FDA to reject the BLA. Quite the contrary: according to the complaint, on February 13, 2020 – *after* the FDA “completed its initial review” – the agency granted Priority Review for the liso-cel application, thereby “*shortening* the approval timeline from ten months to just six.” *Id.* ¶ 50 (emphasis added). As a result, the BLA was assigned an action date of August 17, 2020 under the Prescription Drug User Fee Act (“PDUFA”) – “comfortably four months” before the December 31, 2020 milestone date.⁶ *Id.* ¶ 6.

On April 15, 2020, BMS submitted information in response to an FDA request for supporting “data on assays and validation” relating to the CMC module. *Id.* ¶ 53. Weeks later, the complaint alleges, the FDA concluded that the data BMS had supplied was so substantial that it constituted a “major amendment” to the BLA, which “automatically triggered a three-month

⁵ The Trustee does not base any claim on its allegations concerning ide-cel. *See* Compl. ¶¶ 1, 87-95.

⁶ According to the complaint, “[t]he PDUFA date is of critical importance” because the FDA “strives to approve or deny” BLAs “by the PDUFA date at least 90% of the time” and, “[i]n reality,” it “does even better.” *Id.* ¶ 49.

extension of the PDUFA date” to November 16, 2020 – still “weeks *before* the December 31, 2020” milestone date. *Id.* (emphasis added). The Company promptly disclosed this development. *See id.* ¶ 56.⁷

During the same general period as these alleged developments, the rapid global spread of COVID-19 was declared a worldwide pandemic, the pandemic was declared a national emergency in the United States, and pandemic-related operating restrictions began to significantly impact the FDA, including in its ability to conduct facility inspections for pending applications.⁸ *See* Compl. ¶ 62. Illustrating the eventual impact of the pandemic, the number of approved BLAs plummeted from 21 and 22 in FY 2018 and 2019, respectively, to **only 8** in FY 2020 (ending September 30, 2020) and **only 2** (to date) in the current fiscal year (the BLAs for liso-cel and ide-cel).⁹ The complaint does not mention this reduction in the FDA approval rate or provide an explanation for it.

⁷ The director of the FDA’s Center for Biologics Evaluation and Research acknowledged in public remarks a few weeks after this BMS disclosure that CBER had not been consistent in how it evaluated cell therapy applications. *See* “Top US FDA Official Says New Playbook Needed for CMC Reviews of Gene Therapy Products,” *The Pink Sheet*, June 18, 2020 (“I know that someone out there will say, ‘we had two different CMC reviewers and two different pieces of advice.’ I am not going to argue with that. That is an issue here. As we come to the post-COVID period we should try to have more unity in what comes from our CMC reviews. I cannot say the problem is solved[,] but the problem has been identified and is amenable to solutions.”).

⁸ *See* World Health Org., “WHO Director-General’s Opening Remarks at the Media Briefing on COVID-19 – 11 March 2020” [bit.ly/2W2h8Md]; Executive Office of the President, Proclamation 9994, 85 Fed. Reg. 15337 (Mar. 13, 2020) (declaring national emergency); FDA Statement, “Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections,” Mar. 18, 2020 [bit.ly/3zjHM1u]. These developments are generally known and not subject to reasonable dispute. Fed. R. Evid. 201(b); *100 Orchard St., LLC v. Travelers Indem. Ins. Co. of Am.*, 2021 WL 2333244, at *1 n. 4 (S.D.N.Y. June 8, 2021) (Furman, J.) (taking judicial notice of order directing emergency closure of “non-essential businesses” due to the pandemic).

⁹ FDA Center for Biologics Evaluation and Research, *Biologics Approvals by Year* [bit.ly/3BzqTBR].

The complaint asserts that BMS further breached its covenant to use Diligent Efforts by allegedly “fail[ing] to take the steps necessary to prepare two [l]iso-cel manufacturing facilities for the FDA’s inspections.” Compl. ¶ 9. But while labelling the two inspections as “calamitous,” *id.* ¶ 78, the complaint acknowledges that both inspections were completed and FDA follow-up comments were addressed *before* the liso-cel milestone date. *Id.* ¶¶ 10, 67, 72. The complaint does not address the effects of the pandemic on the FDA’s ability to promptly complete the two facility inspections, even though it alleges that the pandemic caused the agency “to selectively deploy its resources” in handling facility inspections. *Id.* ¶ 62.

D. The Trustee’s Request to Examine Records

In a letter to BMS dated December 29, 2020, the Trustee allegedly requested to inspect six broad categories of information related to the BLA for liso-cel. *Id.* ¶ 75; *see* CVR Agreement, § 4.2(f).¹⁰ According to the complaint, “[p]roviding the information should have been easy for [BMS].” Compl. ¶ 75. The complaint alleges that BMS “refused to provide any information.” *Id.* However, the CVR Agreement terminated automatically less than two days after the Trustee allegedly sent the request when the FDA did not act on the liso-cel application by its milestone date. *Id.* ¶¶ 16, 79.

¹⁰ Section 4.2(f) provides, in part:

. . . the Trustee in its discretion may make such further inquiry or investigation into such facts or matters as it may see fit, and if the Trustee shall determine to make such further inquiry or investigation, it shall be entitled to examine the pertinent books and records of the Company, personally or by agent or attorney, as may be reasonably necessary for such inquiry or investigation and in a manner so as to not unreasonably interfere with the normal business operations of the Company or any of its Affiliates; provided, however, that [the] Company shall not be required to provide any books or records to the extent that the provision thereof (i) would, as reasonably determined based on the advice of outside counsel, jeopardize any attorney-client privilege or (ii) would contravene any Law or any contract or agreement to which the Company or any of its Affiliates is subject or bound[.]

E. The Claims Asserted and the Trustee’s Untimely Notice

In a written notice to BMS dated March 4, 2021 – more than two months *after* the CVR Agreement terminated automatically – the Trustee purported to notify BMS that it “was in Default under the CVR Agreement because . . . [the Company] had breached its obligations to use Diligent Efforts to achieve the Liso-cel Milestone and to allow the Trustee to investigate [the Company’s] books and records.” *Id.* ¶ 86. The complaint alleges that BMS “has not cured these breaches for over ninety days,” *id.*; *see also id.* ¶¶ 93, 102, but the Trustee does not attempt to explain how the Company could do so given the termination of the CVR Agreement, the expiration of the milestone date, and the FDA’s approval of liso-cel long before the Trustee allegedly sent the notice.

The complaint asserts two claims for breach of the CVR Agreement against BMS: first, for the Company’s alleged “fail[ure] to use Diligent Efforts to achieve the Liso-cel Milestone,” *id.* ¶ 89, and second, for its alleged “fail[ure] to provide the Trustee access to its books and records[.]”, *id.* ¶ 99.

MOTION TO DISMISS STANDARD

To survive a Rule 12(b)(6) motion to dismiss, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A facially plausible claim is one that enables the court “to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. The plaintiff “must allege sufficient facts to show ‘more than a sheer possibility that a defendant acted unlawfully.’” *OneWest Bank, N.A. v. Lehman Bros. Holding Inc.*, 2015 WL 1808947, at *2 (S.D.N.Y. Apr. 20, 2015) (Furman, J.) (quoting *Iqbal*, 556 U.S. at 678). “If the plaintiff has not ‘nudged [his or her] claims across the line from conceivable to plausible, [the] complaint must be dismissed.”

Oppenheimer & Co. v. Trans Energy, Inc., 946 F. Supp. 2d 343, 347 (S.D.N.Y. 2013) (quoting *Twombly*, 550 U.S. at 570).

ARGUMENT

I. THE ADMITTED FAILURE TO PROVIDE TIMELY PRE-SUIT NOTICE REQUIRES DISMISSAL OF THE TRUSTEE’S “DILIGENT EFFORTS” CLAIM.

The Trustee’s claim for alleged breach of the covenant to use Diligent Efforts to obtain FDA approval of liso-cel by the contractual milestone date should be dismissed. The Trustee did not comply with the contract’s pre-suit notice requirement for this alleged default, and no Event of Default therefore ever arose with respect to it. No suit for breach of the CVR Agreement can be maintained by the Trustee under the circumstances.

A. New York Law on Motions to Dismiss Breach of Contract Claims.

To recover for breach of contract under New York law, a plaintiff must establish “(1) the existence of a contract between itself and the defendant; (2) performance of the plaintiff’s obligations under the contract; (3) breach of the contract by the defendant; and (4) damages to the plaintiff caused by that defendant’s breach.” *Diesel Props. S.r.l. v. Greystone Bus. Cred. II LLC*, 631 F. 3d 42, 52 (2d Cir. 2011); *see Nat’l Mkt. Share, Inc. v. Sterling Nat’l Bank*, 392 F. 3d 520, 525 (2d Cir. 2004) (“[c]ausation is an essential element of damages in a breach of contract action”).¹¹

“[T]he initial interpretation of a contract ‘is a matter of law for the court to decide[.]’” *Svensson v. Securian Life Ins. Co.*, 706 F. Supp. 2d 521, 525 (S.D.N.Y. 2010) (quoting *K. Bell & Assocs. v. Lloyd’s Underwriters*, 97 F.3d 632, 637 (2d Cir. 1996)). The goal in that analysis is “to give effect to the intention of the parties as expressed in the unequivocal language they have

¹¹ The parties agree that the CVR Agreement is governed by New York law. Compl. ¶ 27; *see* CVR Agreement, § 1.10.

employed.” *BNP Paribas Mortg. Corp. v. Bank of Am., N.A.*, 866 F. Supp. 2d 257, 269 (S.D.N.Y. 2012) (quoting *Wallace v. 600 Partners Co.*, 86 N.Y.2d 543, 548, 634 N.Y.S.2d 669, 671 (1995)).

Whether a “contract is unambiguous is a question of law for the court.” *Cont'l Ins. Co. v. Atl. Cas. Ins. Co.*, 603 F.3d 169, 180 (2d Cir. 2010). “A contract is unambiguous where it has ‘a definite and precise meaning, unattended by danger of misconception in the purport of the contract itself, and concerning which there is no reasonable basis for a difference of opinion.’” *N.Y. Wheel Owner LLC v. Mammoet Hldg. B.V.*, 481 F. Supp. 3d 216, 244 (S.D.N.Y. 2020) (Furman, J.) (quoting *Olin Corp. v. Am. Home Assur. Co.*, 704 F.3d 89, 99 (2d Cir. 2012)). “When a contract’s language is unambiguous, a court may resolve a claim for breach of contract on a motion to dismiss.” *N.Y. Wheel*, 481 F. Supp. 3d at 244 (collecting cases). Application of these principles requires dismissal of the Trustee’s claim for alleged breach of the covenant to use Diligent Efforts.

B. The Trustee’s Failure to Plead an Event of Default for Alleged Breach of the Diligent Efforts Provision Requires Dismissal.

Under the CVR Agreement, no suit for breach of the Company’s covenant to use Diligent Efforts can be brought unless formal written notice of the alleged breach is first provided to the Company requiring it to be remedied *and* that breach continues for ninety days after the notice is sent. Only then can there be an actionable Event of Default. CVR Agreement, §§ 8.1(b), 8.4. But the Trustee alleges it did not provide the required written notice until months after the CVR Agreement terminated. Compl. ¶ 86. By then, the Company had no further obligation to use Diligent Efforts, the liso-cel milestone date was months in the past, and liso-cel had been approved by the FDA.

Under New York law, “if a contract explicitly states that notice and an opportunity to cure are conditions precedent to bringing or maintaining a claim, courts will enforce that agreement.”

Rojas, 2012 WL 760336, at *2 (dismissing complaint) (collecting cases); *see U.S. Bank*, 2004 WL 1699057, at *3 (applying New York law in dismissing breach of contract claim brought by indenture trustee where lack of notice meant there was no Event of Default that would permit the trustee to sue under the terms of the indenture).

Because providing notice of breach and an opportunity to cure are conditions precedent to the right to sue, “[s]trict compliance is required.” *E. 18th Mgmt. Corp. v. CSC ServiceWorks, Inc.*, 2019 WL 2994447, at *7 (E.D.N.Y. July 9, 2019). “Substantial performance is not enough[.]” *Id.* at *7; *see Prudential Ins. Co. of Am. v. Hilton Hotel Corp.*, 1996 WL 34002, at *3 (S.D.N.Y. June 19, 1996) (dismissing claim under joint venture agreements where plaintiff did not provide contractually required notice of default before filing suit); *I.J. Litwak & Co. v. Gen. Signal Corp.*, 741 N.Y.S.2d 426, 427 (2d Dep’t 2002) (*per curiam*) (ordering dismissal of lease action based on plaintiff’s failure to provide written notice of default and opportunity to cure); *see also N.Y. Wheel*, 481 F. Supp. 2d at 246 (Furman, J.) (where contract provides that failure to comply with contractual notice requirements “would constitute a waiver” of claim for damages, notice requirements will be enforced).

Under the CVR Agreement, the Trustee can sue BMS only when there has been an Event of Default. CVR Agreement, § 8.4; *see also id.* § 8.1 (“If an Event of Default described above occurs and is continuing, then, and in each and every case,” the Trustee “shall bring suit to protect the rights of the Holders”).¹² But there cannot be an Event of Default arising from an alleged

¹² Section 8.4 provides:

Suits for Enforcement. In case an Event of Default has occurred, has not been waived and is continuing, the Trustee may in its discretion proceed to protect and enforce its rights and the rights of the Holders under this CVR Agreement by such appropriate judicial proceedings as the Trustee shall deem most effectual to protect and enforce any of such rights, either at Law or in equity or in bankruptcy or otherwise, whether for the specific enforcement of any covenant or agreement contained in this CVR Agreement or

breach of the Company's covenant to use Diligent Efforts unless the Trustee first provides, "by registered or certified mail," a "written notice specifying such . . . breach and requiring it be remedied" and the putative breach then "continu[es] . . . for a period of ninety (90) days after" the formal written notice has been provided. *Id.* § 8.1(b);¹³ *see U.S. Bank*, 2004 WL 1699057, at *3 ("Without notice, there is no Event of Default, and without an Event of Default, the Trustee has no power to bring any claim."); *see also UMB Bank, N.A. v. Neiman Marcus Grp., Inc.*, 128 N.Y.S.3d 823, 826 (N.Y. Sup. Ct. 2020) (indenture trustee lacked authority under indenture to bring suit before occurrence of Event of Default).

The complaint recognizes these pre-suit requirements and purports to allege the Trustee's compliance with them. *See* Compl. ¶¶ 86, 92-94, 101-03. But the notice alleged in the complaint did not, and could not, comply with the requirements of the CVR Agreement. The Trustee alleges it sent BMS a formal written notice of the Company's alleged breaches on March 4, 2021. Compl.

in aid of the exercise of any power granted in this CVR Agreement or to enforce any other legal or equitable right vested in the Trustee by this CVR Agreement or by Law.

¹³ Section 8.1 defines an "Event of Default" under the CVR Agreement. Section 8.1(b) provides:

"Event of Default" with respect to the Securities, means each one of the following events which shall have occurred and be continuing (whatever the reason for such Event of Default and whether it shall be voluntary or involuntary or be effected by operation of Law or pursuant to any judgment, decree or order of any court or any order, rule or regulation of any administrative or governmental body):

[* * *]

(b) material default in the performance, or breach in any material respect, of any covenant or warranty of the Company in respect of the Securities (other than a covenant or warranty in respect of the Securities, a default in whose performance or whose breach is elsewhere in this Section 8.1 specifically dealt with), and continuance of such default or breach for a period of ninety (90) days after there has been given, by registered or certified mail, to the Company by the Trustee or to the Company and the Trustee by the Majority Holders, a written notice specifying such default or breach and requiring it to be remedied and stating that such notice is a "Notice of Default" hereunder[.] . . .

¶ 86. However, the CVR Agreement terminated automatically months earlier, at 12:01 a.m. on January 1, 2021, after the liso-cel milestone date lapsed with no FDA decision on that application. *Id.* ¶ 79; *see* CVR Agreement, § 1.16. Immediately upon termination of the CVR Agreement, the parties had no further “obligations [t]hereunder” and the Company’s covenant to use Diligent Efforts to achieve the liso-cel milestone ceased to have “force or effect.” CVR Agreement, § 1.16.¹⁴

There could be no “continuance” of any alleged breach of the covenant for the ninety days that followed the Trustee’s belated notice because the Company did not have any further obligation to perform under that provision by the time the Trustee sent it. *Id.* § 8.1(b); *see Int’l Techs. Mktg., Inc. v. Verint Sys. Ltd.*, 157 F. Supp. 3d 352, 363 (S.D.N.Y. 2016), *aff’d*, 850 F. App’x 38 (2d Cir. 2021) (under New York law, “[w]hen a contract is terminated, such as by expiration of its own terms, the rights and obligations thereunder cease.”) (quoting *Twitchell v. Town of Pittsford*, 483 N.Y.S. 2d 524, 525 (4th Dep’t 1984), *aff’d mem.* 66 N.Y.2d 824 (1985)). As a result, it was not possible for alleged breaches specified in the Trustee’s untimely notice to become an Event of

¹⁴ Section 1.16 provides, in part:

Termination. This CVR Agreement will, automatically and without any further action of any Party, terminate and be of no force or effect, and the Parties hereto shall have no liability or obligations hereunder, at the following time (the “Termination Date”): (a) if as of the end of the day on the Initial Milestone Target Date, either the JCAR017 Milestone or the Ozanimod Milestone has not occurred, 12:01 a.m. New York City time on the calendar day following the Initial Milestone Target Date, (b) . . . or (c) if the Milestone has been achieved, the calendar day following the date on which the Trustee has paid the Milestone Payment to the Holders in accordance with Section 3.1(c); provided, however, that (A) Sections 1.5, 1.6, 1.7, 1.8, 1.9, 1.10, 1.12, 1.13, 4.7, 7.5, 7.9, 7.10, Article 8, this Section 1.16 and Section 1.1 (to the extent related to the foregoing) shall survive termination of this CVR Agreement in accordance with their terms; and (B) the termination of this CVR Agreement shall not relieve any Party of any liability arising from any material breach of its obligations under this CVR Agreement occurring prior to the Termination Date. . . .

Default, *see* CVR Agreement, § 8.1(b), and the Trustee is not empowered under the terms of the agreement to bring a legal action based on them, *id.* §§ 8.1, 8.4; *see U.S. Bank*, 2004 WL 1699057, at *3 (“the powers of the Trustee are defined by and limited by the terms of the Indenture. The power of the Trustee to sue the Issuer pursuant to section 6.3 is contingent on the occurrence of an Event of Default”).

Nor was it possible for an alleged failure to use Diligent Efforts to achieve the liso-cel milestone to be “remedied” given that the written notice was sent after the FDA already had approved liso-cel and months after the liso-cel milestone date already had passed. *See* CVR Agreement, § 8.1(b). No amount of “efforts” could turn back time, nor could BMS change the fact that the FDA already had approved liso-cel on February 5, 2021 – a month before the alleged notice. *See* Compl. ¶ 5, 80. Thus, the Trustee’s notice was not a good faith attempt to bring an alleged breach to the Company’s attention so that it might be addressed without litigation. It was, instead, a belated attempt to “check a box” under the CVR Agreement in anticipation of a motion to dismiss a future complaint that the Trustee already knew it would be filing.¹⁵

Section 1.16 of the CVR Agreement, providing for termination of the contract “without further action of any Party” in specified circumstances, also provides that delineated provisions will survive termination. But the covenant to use Diligent Efforts, contained in section 7.8 of the

¹⁵ The CVR Agreement excludes some types of breach from the pre-suit notice-and-cure requirements. For example, if all of the milestones had been met and the Company then failed to make payment to CVR holders within ten business days, that would have been an Event of Default for which the Trustee could have sued immediately. *See* CVR Agreement, § 8.1(a). The pre-suit notice procedures required before the Trustee can sue for other alleged breaches is unequivocally intentional and must be enforced. *Lockheed Martin Corp. v. Retail Holdings NV*, 639 F.3d 63, 69 (2d Cir. 2011) (“If the document as a whole ‘makes clear the parties’ over-all intention, courts examining isolated provisions should then choose that construction which will carry out the plain purpose and object of the [agreement].’”) (quoting *Kass v. Kass*, 91 N.Y.2d 554, 567, 673 N.Y.S.2d 350, 357 (1998)).

agreement, is not one of those provisions. *See* CVR Agreement, § 1.16(A). Nor is the Trustee’s belated notice excused by the survival of “Article 8,” *id.*, or by the proviso that “termination of the CVR Agreement shall not relieve any Party of any liability arising from any material breach of its obligations . . . occurring prior to the Termination Date.” *Id.* § 1.16(B).

Those exclusions permit the Trustee to sue after termination if there has been an Event of Default. *See id.* § 8.4. But they do not alter the definition of an Event of Default provided in section 8.1(b). Even after termination, the Trustee cannot sue for an alleged breach of the covenant to use Diligent Efforts unless that breach has continued for ninety days after the required written notice of default. *Id.* § 8.1(b). For the reasons already discussed, that cannot occur for an alleged breach of the covenant to use Diligent Efforts because the covenant ceases to have “force or effect” upon termination. It also could not occur in this instance because the milestone date had passed and the FDA already had approved the liso-cel application.

Considered against the actual terms of the CVR Agreement, the Trustee’s untimely written notice is legally equivalent to providing no notice at all. “Where no notice is given under the contract, there can be no breach because the counter-party has not been afforded the opportunity to cure the defect.” *Vision Entm’t Worldwide, LLC v. Mary Jane Prods., Inc.*, 2014 WL 5369776, at *10 (S.D.N.Y. Oct. 17, 2014) (citing *I.J. Litwak & Co.*, 741 N.Y.S.2d at 426); *USI Ins. Servs. LLC v. Miner*, 801 F. Supp. 2d 175, 182 (S.D.N.Y. 2011) (same); *see also E. 18th Mgmt.*, 2019 WL 2994447, at *5 (“The court interprets the notice-and-cure provision to mean that each party cannot be in breach of the lease unless it was first provided with notice of any claimed breach and a 60-day opportunity to cure any claimed breach.”).¹⁶

¹⁶ The Trustee’s allegations preclude any contention that providing timely notice of an alleged breach of the Diligent Efforts provision would have been futile. As Judge Buchwald explained, the “limited” futility exception applies only when an allegedly breaching party

The plain language of the CVR Agreement is clear. Just as in *U.S. Bank*, “[w]ithout notice, there is no Event of Default, and without an Event of Default, the Trustee has no power to bring any claim.” 2004 WL 1699057, at *3. The Trustee’s claim against the Company for alleged breach of the Diligent Efforts provision therefore should be dismissed. *See E. 18th Mgmt.*, 2019 WL 2994447, at *7 (“The court must enforce express conditions, even if enforcement would result in a harsh outcome, because they are a manifestation of the parties’ intent.”); *Rojas*, 2012 WL 760336, at *3 (“because the complaint fails to allege compliance with the provision in even general terms, Rojas has failed to state a claim for breach of contract”).

II. THE CLAIM FOR ALLEGED REFUSAL TO PERMIT EXAMINATION OF THE COMPANY’S BOOKS AND RECORDS ALSO SHOULD BE DISMISSED.

The Trustee’s claim for alleged breach of the Trustee’s right “to examine the pertinent books and records of the Company” also should be dismissed. *See* CVR Agreement, § 4.2(f); Compl. ¶¶ 96-105. The complaint alleges the Trustee sent BMS a letter requesting six broad categories of records on December 29, 2020, two days before the liso-cel milestone date, which the complaint alleges the Company “refused to comply with.” Compl. ¶¶ 15, 75, 77. The Trustee seeks monetary damages for this alleged breach measured by its expenses to engage in an investigation allegedly made necessary by the Company’s “fail[ure] to provide the Trustee access

“expressly repudiates the parties’ contract” or “abandons performance thereunder.” *Point Prods. A.G. v. Sony Music Entm’t Inc.*, 2000 WL 1006236, at *4 (S.D.N.Y. July 20, 2000) (citing *Bausch & Lomb Inc. v. Bressler*, 977 F.2d 720, 728 (2d Cir. 1992); *Wolff & Munier, Inc. v. Whiting-Turner Contracting Co.*, 946 F.2d 1003, 1009 (2d Cir. 1991)); *see Vision Entm’t*, 2014 WL 5369776, at *10 (applying exception given undisputed repudiation). There are no such allegations here. To the contrary, the Trustee alleges that, in addition to obtaining FDA approval for all three applications, BMS continued to press for FDA approval of liso-cel right up to the December 31, 2020 milestone date. *See, e.g.*, Compl. ¶ 72 (BMS response to observations from Lonza facility inspection submitted “on December 23, 2020, just days before the Liso-Cel Milestone”).

to” the requested books and records. Compl. ¶ 99. This claim should be dismissed for several reasons.

First, the Trustee failed to provide the Company timely written notice of its alleged breach of section 4.2(f) before suing. The complaint alleges that the Trustee notified the Company of the breach on March 4, 2021, in the same written notice discussed above. Compl. ¶¶ 86, 101. But for the reasons already discussed, that written notice was untimely. Section 4.2(f) did not survive the automatic termination of the CVR Agreement. *See* CVR Agreement, § 1.16. As a result, the alleged breach of section 4.2(f) did not and could not “continu[e] . . . for a period of ninety (90) days” following the notice or turn into an Event of Default. *Id.* § 8.1(b). As with the claim for alleged breach of the Diligent Efforts provision, the claim for alleged breach of section 4.2(f) should be dismissed because there is no Event of Default that would permit the Trustee to sue. *See id.* §§ 8.1, 8.4; *U.S. Bank*, 2004 WL 1699057, at *3.

Second, the Trustee’s decision to send its request to examine records just two days before the CVR Agreement automatically terminated is also fatal. Section 4.2(f) ceased to have any continuing “force or effect” once the CVR Agreement terminated on January 1, 2021, and thereafter the Company had no further obligation to permit examination of “pertinent books and records.” CVR Agreement, § 1.16. Nor did the provision require BMS to permit the requested examination immediately upon its receipt of the Trustee’s request, as the complaint implies. No breach of section 4.2(f) could have arisen in the two days that the contract remained in effect after the Trustee allegedly sent its request. *See* Compl. ¶ 77 (accusing BMS of “running out the clock” on books and records request).

Section 4.2(f) permits the Trustee to examine “the pertinent books and records of the Company” to the extent “reasonably necessary for” an investigation into matters concerning the

CVR Agreement. CVR Agreement, § 4.2(f). However, such a request must be made “in a manner so as to not unreasonably interfere with the business operations of the Company or any of its Affiliates[.]” *Id.* The request letter here was sent “in the middle of the winter holidays,” as the complaint elsewhere observes, Compl. ¶ 72, at a time of the year when most corporations would not be well-positioned to respond immediately to unexpected information requests. Moreover, on December 29, 2020, the milestone date for the liso-cel application was less than two days away. Taking time away from normal duties to respond to the request undoubtedly would have “unreasonably interfere[d]” with important “business operations,” including those that might have been associated with the pending application. CVR Agreement, § 4.2(f).

Section 4.2(f) as a whole cannot reasonably be read to require instantaneous production of records, as the complaint appears to assume. *See* Compl. ¶ 77. The section provides, *inter alia*, that:

. . . the Company shall not be required to provide any books and records to the extent that the provision thereof (i) would, as reasonably determined based on the advice of outside counsel, jeopardize any attorney-client privilege or (ii) would contravene any Law or contract or agreement to which the Company or any of its Affiliates is subject or bound.

CVR Agreement, § 4.2(f). Before making “pertinent books and records” available for the Trustee to examine, the provision anticipates that the Company and its outside counsel will be provided the time necessary to review materials to ensure they do not include information the Company is contractually entitled to withhold. An alleged failure to provide access to records in less than two days cannot be a breach of the provision given the time the section expressly permits for such a pre-examination review.

Finally, the alleged damages sought for this putative breach – expenses incurred by the Trustee “to engage in an investigation that would have been obviated or reduced in scope” if BMS had complied with section 4.2(f), Compl. ¶ 104 – are not legally cognizable. Under New York

law, a plaintiff only can recover “damages that are ‘direct[ly] and proximate[ly]’ caused by a defendant’s breach of contract.” *Nat'l Mkt. Share, Inc.*, 392 F.3d at 526 (quoting *Wakeman v. Wheeler & Wilson Mfg. Co.*, 101 N.Y. 205, 209 (1886)); *see Kenford Co. v. Co. of Erie*, 67 N.Y.2d 257, 261, 502 N.Y.S.2d 131, 132 (1986) (*per curiam*) (“the alleged loss must be capable of proof with reasonable certainty” and “damages may not be merely speculative, possible or imaginary, but must be reasonably certain and directly traceable to the breach, not remote or the result of other intervening causes”).

The complaint does not plausibly allege that the Trustee’s costs of investigation, incurred *after* the CVR Agreement automatically terminated, were “directly” and “proximately” traceable to the Company’s alleged failure to permit examination of books and records in response to a letter that the Trustee sent with no advance notice “in the middle of the winter holidays.” Compl. ¶ 72.

CONCLUSION

For the foregoing reasons, the complaint should be dismissed.

Dated: New York, New York
July 23, 2021

DLA PIPER LLP (US)

By: /s/ John J. Clarke, Jr.
John J. Clarke, Jr.
john.clarke@dlapiper.com
Jessica A. Masella
jessica.masella@dlapiper.com
Jessica Park Wright
jessica.wright@dlapiper.com

1251 Avenue of the Americas
New York, New York 10020-1104
(212) 335-4500

Attorneys for Defendant
Bristol-Myers Squibb Company